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Claim 37: The method of claim 27, wherein said gene encodes a human polypeptide, the amino acid sequence of which is encoded by the nucleotide sequence set forth in SEQ ID NO: 32.

Claim 38: The method of Claim 27, wherein said gene encodes a human polypeptide, the amino acid sequence of which is set forth in SEQ. ID NO.: 37.

REMARKS

Entry of the foregoing amendment is requested. Newly submitted Claims 37 and 38 are supported by the specification, and are submitted in accordance with 37 CFR § 1.121(h).

Claims 27-36 have been rejected under 35 USC § 112, first paragraph, as allegedly not satisfying the written description requirement. According to the examiner:

> "(O)nly an isolated nucleic acid molecule comprising a nucleic acid consisting of SEQ. ID NO.: 12, 14-18, 21-22, 24-25, 27 or 29, but not the full breadth of the claims meets the written description provision of 35 USC § 112, first paragraph.

This rejection is traversed.

First, assuming arguendo that the rejection is proper, why are Claims 32 and 33, which recite these specific sequences, rejected?

Second, review of the sequences which the examiner admits are described reveals that, e.g., SEQ. ID NOS.: 12 and 14.

48 AARATGGAYT GGATHTTYCA YAC (SEQ. ID NO.: 12)

and

GATGATGGCC ARCTGTTYCA YATWGAYTTT GGGCA

(SEQ. ID NO.: 14)

collectively encompass 80 nucleic acid molecules, due to variables "R," "Y," "H" and "W."

SEQ. ID NOS.: 27 AND 29:

GGNGAY GAYY TRCGNCARGA

(SEQ. ID NO.: 27)

and

RAARTGCCRA ARTCDATRTG RAA

(SEQ. ID NO.: 29)

collectively cover 448 nucleic acid molecules. In toto, then, the examiner agrees that the specification provides adequate written description for over 500 probes - yet concludes that the claims do not satisfy 35 USC § 112.

The cases relied upon by the examiner, i.e., Vas-Cath v. Mahurkar, 19 USPQ2d 111 and Reagents of the University of California v. Eli Lilly, 43 USPQ2d 1398, are not relevant here. In Vas-Cath, the issue was whether a priority document could be used to support a priority claim, when material was added to a subsequent case. The Reagents of the University of California case involved a claim to cDNA that encoded human insulin, where no sequence was described at all. Such is decidedly not the case here. As was pointed out, supra, nearly 500 oligonucleatides are described in the specification, which all support the claims. The examiner concedes this.

The "Interim Written Description Guidelines" referred to by the examiner do not support the rejection, as these are quite clear that where there is description of the type presented in this application, there is adequate written description. As such, the rejection is improper, and should be withdrawn.

The examiner has also rejected Claims 27-36 under 35 USC § 112, first paragraph, arguing that while the specification enables methods which use nucleic acid molecules which use SEQ. ID NOS.: 12, 14-18, 21, 22, 24, 25, 27 and 29, does not enable any of the pending claims. The rejection is traversed.

As with the written description rejection, applicants query why Claims 32 and 33 are rejected, as these recite what the examiner concedes is enabled.

The claim recites that the nucleic acid must "hybridize specifically" to the recited nucleic acid molecule. The language used is not that employed by the examiner, i.e.:

> "Many nucleic acid molecules that hybridize to a transcript of the gene will not be an indicator of a human polypeptide having PI3 kinase activity and a molecular weight of about 110kD as determined by SDS-PAGE."

The examiner has omitted the modifier "specifically." Such language is key to the invention, and the claim should be construed correctly. Contrary to the examiner's position, i.e., "The claims must recite SEQ ID NO's in the claims," no such rule exists.

The claims allegedly "broadly teach the contacting a sample with a nucleic acid molecule which hybridize to a transcript gene." As was pointed out, supra, the language in the claim is "hybridize specifically." Applicants do not know what is meant by a "transcript" gene, and in any event, the claims require hybridization to a transcript of a gene encoding a protein with a specific function.

Over 500 sequences are provided, for which the examiner concedes there is enablement for this. The examiner, in contrast, has not provided a single example of a sequence which meets the listed criteria that does not satisfy the claim.

The examiner contends that hybridization conditions are not taught. With respect to this, please note page 6, lines 30-37 of the specification. Claims are interpreted in light of the specification. There are clear guidelines as to what the terms mean. As such, the rejection of claims 27-36 at points 6 and 7 are improper, and should be withdrawn. The examiner's statement, in connection with this rejection:

> "(T)he use of the PI3 kinase polypeptide of Skolnik et al., in view of Carpenter et al., could hybridize to any of the sequences disclosed in claims 32 and 33"

is not understood. Skolnik teaches polypeptides, not DNA. Previously, in the parent applications of this case, the USPTO required restriction between DNA and peptides. The USPTO has thus taken the position that these are distinct.

Further, there is no evidence that peptide sequences could hybridize to DNA. Even if they could, such would not impact what is claimed.

The examiner then states "Applicant's arguments filed December 11, 2000 have been fully considered but they are not persuasive." This is an incomplete response. The MPEP requires examiners to respond to arguments proffered by the applicant. The above statement, which represents the examiner's total response, is clearly incomplete.

The rejection of Claim 36 under 35 USC § 112, second paragraph, is also not understood. The examiner calls for definition of a "standard." A standard is not needed. One of ordinary skill in the art knows that in molecular biology, controls are used, rather than a "standard." A "control" can be an experiment carried out in parallel with a second experiment designed to test a variable. In the control, all parameters are the same as those used in the second experiment, with the exception of a variable. One can certainly carry out such an experiment to determine quantitative differences, but in some cases, a qualitative difference is all that is desired. That is what Claim 36 defines, i.e., a qualitative assay. The examiner is attempting to define it as a quantitative assay. There is no basis for this.

The examiner has rejected Claims 27-35 under 35 USC § 103 over Skolnik in view of Carpenter. According to the examiner:

> "(I)t would have been obvious at the time of applicant's invention to have used the 110kD protein as taught by Carpenter et al. in the method of determining gene expression as taught by Skolnik et al., because Carpenter et al. teaches that the 110kD protein was isolated by SDS-PAGE, is correlated to the PI3 kinase activity, strongly related to cell growth activity, its gene products can be found of different genes and is crucial in intracellular signals which respond to a number of hormones and growth factors."

The rejection, to the degree it is understood, is traversed.

The claims relate to nucleic acid hybridization assays. Skolnik does not. What Skolnik teaches is that the carboxy terminal tort of EGFR can be used to screen expression libraries. The reference describes how EGFR binds to other proteins. It does not describe a hybridization assay where nucleic acid molecules hybridize.

It is not seen how using the 110kD protein of Carpenter in the Skolnik method would have rendered the invention obvious. What is the substitution proposed? Is the examiner suggesting substituting the rat protein of Carpenter for the EGFR carboxy terminus, to determine what proteins would bind to the rat protein, or is the examiner suggesting that the rat DNA be used in an expression library to determine if it binds to EGFR carboxy terminus? Neither result even remotely approaches what is claimed. It is not seen how a DNA hybridization assay can be secured, using the cited art. Nothing within the references, or the examiner's argument, suggests it.

In view of the foregoing, withdrawal of the rejection is believed proper, and is urged.

All objections have been addressed and overcome. It is believed that the application is now allowable, and a notice to that end is urged.

Respectfully submitted,

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